

Amendments to the Specification:

Please replace the paragraph beginning on page 5, line 21 with the following amended paragraph:

SUMMARY OF THE INVENTION

The present invention is directed to methods for the inhibition of post-operative adhesion formation in a body between tissue surfaces in a body cavity having been subjected to a surgical procedure comprising administering Pemirolast, or an analog thereof, directly to tissue surfaces in the body cavity in amounts and under conditions effective to inhibit formation of adhesions thereon, and to delivery vehicles and compositions suitable for use for non-systemic administration of a drug directly to tissue within a body cavity having been subjected to a surgical procedure, where the vehicle or composition comprises Pemirolast Tranilast in an amount effective to inhibit formation of post-operative adhesions upon administration of the Pemirolast Tranilast to the tissue under conditions effective to provide inhibition of post-operative adhesions in the body cavity.

Please replace the paragraph beginning on page 9, line 23 with the following amended paragraph:

The therapeutically effective concentrations of Pemirolast or analogs thereof are ones that inhibit or prevent post-surgical adhesion formation between tissue surfaces in body cavities having undergone surgery when applied to tissue in the body cavity. The minimum amount of Pemirolast or analogs thereof that can be administered must be effective to inhibit formation of the postoperative adhesion, as described herein. The maximum amount of Pemirolast or analog thereof that may be administered is limited by the toxicity of the compound. In general, the range of concentration of Pemirolast Tranilast administered to the body will be from about 0.01 milligram Pemirolast per kilogram of the body to about 3,000 milligram Pemirolast per kilogram of the body.

Please replace the paragraph beginning on page 11, line 4 with the following amended paragraph:

A large variety of alternative sustained release delivery vehicles for administering Pemirolast or analogs thereof also are contemplated as within the scope of the present invention when containing therapeutically effective amounts of Pemirolast. Suitable delivery vehicles include, but are not limited to, microcapsules or microspheres; liposomes and other lipid-based release systems; absorbable and/or biodegradable mechanical barriers; emulsions, the emulsion either being a liquid polymer plus surfactant or a non-aqueous polymer solution plus surfactant in an aqueous carrier; polymeric delivery materials such as, but not limited to, polyethylene oxide/polypropylene oxide block copolymers (i.e., poloxamers), poly(orthoester)s, poly(vinyl alcohol)s, poly(anhydride)s, poly(methacrylate)s, poly(methacrylaldehyde)s, anionic carbohydrate polymers, poly(hydroxybutyric acid)s, and polyacetals. Most preferably, a suitable formulation to achieve the most desired release profile of Pemirolast Tranilast, near pseudo zero-order, comprises injectable microcapsules or microspheres prepared from a biodegradable polymer such as, but not limited to, poly(1-lactide), poly(dl-lactide), poly(dl-lactide-coglycolide)s, poly(1-lactide-co-glycolide)s, poly(ecaprolactone), polyglycolide, poly(p-dioxanone)s, poly(trimethylene carbonate), poly(alkylene diglycolate)s, poly(oxaester)s, poly(oxaamide)s, glycerides, and copolymers and blends thereof. Other desired release profiles, such as ones that yield an initial burst release of Pemirolast followed by zero-order sustained release, may be created by mixing encapsulated and non-encapsulated drug into the formulation.

Please replace the paragraph beginning on page 19, line 22 with the following amended paragraph:

Therapeutic agents that may be used in combination with Pemirolast may fall in the general classes of anti-platelet, anti-fibrotic, anti-inflammatory, anti-proliferative, and/or inhibit collagen synthesis. These include, but are not limited to, Urokinase, the

nonglycosylated deletion mutein of tissue plasminogen activator available under the tradename RETAVASE (Boehringer Manheim, Indianapolis, IN), pharmaceutical preparations containing abciximab for the prevention and treatment of diseases of the circulatory system available under the tradename REOPRO (Eli Lilly and Company, Indianapolis IN), Clopidogrel Bisulfate, available under the tradename PLAVIX (Sanofi-Synthelabo, Paris, France), pharmaceutical preparations containing imatinib mesylate for use in the field of oncology available under the tradename GLEEVEC (Novartis AG, Basel Switzerland), Triamcinolone Acetonide, Tepoxalin, Pirfenidone, collagenase, anti-CTGF, tyrosine kinase inhibitors, prolyl hydroxylase inhibitors, lysyl oxidase inhibitors, C-proteinase inhibitors, N-proteinase inhibitors, TGF-beta inhibitors such as Tamoxifen, HMG-CoA Reductase inhibitors such as Lovastatin, COX-1 and/or COX-2 inhibitors such as Ibuprofen, Nimesulide, pharmaceutical preparation containing vofecoxib for the treatment of arthritis available under the tradename VIOXX (Merck & Co., Inc. Whitehouse Station NJ), pharmaceuticals in the nature of anti-inflammatory analgesics containing celecoxib available under the tradename CELEBREX (G.D. Searle & Co., Skokie IL), pharmaceutical preparations containing valdecoxib available under the tradename BEXTRA (Pharmacia & Upjohn Co., North Peapack NJ), Calcium ion inhibitors such as Amlodipine, Nifedipine, pharmaceuticals such as verapamil used in the treatment of hypertension, iron chelators such as deferoxamine available under the tradename DESFERAL (Novartis AG, Basel Switzerland), antibiotics such as Clarithromycin and Ciprofloxacin retinoids such as Tretinoin and Retinoic Acid, chymase inhibitors, mast cell stabilizers such as Cromolyn, available under the tradenames OPTICROM or CROLOM (Bausch Lomb Pharmaceuticals, Inc. Tampa, FL), Lodoxamide, available under the tradename ALOMIDE (Alcon Laboratories, Inc. Fort Worth, TX), Nedocromil (ALOCRIL Allergan, Inc. Irvine, CA), Pimecrolimus, available under the tradename ELIDEL (Novartis AG Corporation Basel, Switzerland), Amlexanox, Epinastine, dual action mast cell stabilizers and H1 receptor antagonists such as Olopatadine, available under the tradename PATANOL (Alcon Manufacturing, Ltd Fort Worth, TX), Ketotifen, available under the tradename ZADITOR (Novartis AG Corporation Basel, Switzerland), Azelastine, available under the tradename OPTIVAR (ASTA Medica, Inc., Tewksbury, MA), Pemirolast Tranilast, and analogs thereof, and anti-thrombin drugs or thrombolytics, such as bivalirudin, available under the tradename ANGIOMAX (The Medicines Company,

Cambridge MA). When used in combination with Pemirolast, the therapeutic agents, or drugs, are present in an amount effective to provide the therapeutic effect intended by administration of the therapeutic agent.

Please replace the paragraph beginning on page 24, line 13 with the following amended paragraph:

In the peritoneal sidewall model, rabbits were pre-anesthetized with 1.2 mg/kg acetylpromazine and anesthetized with a mixture of 55 mg/kg ketamine hydrochloride and 5 mg/kg xylazine intramuscularly. Following preparation for sterile surgery, a midline laparotomy was performed. A 3 cm x 5 cm area of peritoneum and transversus abdominis muscle was removed on the right lateral abdominal wall. The cecum was exteriorized and digital pressure was exerted to create subserosal hemorrhages (trauma and loss of blood flow) over all cecal surfaces. The cecum was then returned to its normal anatomic position. Pemirolast ~~Tranilast~~ contained in a delivery vehicle as described below was placed in an Alzet® miniosmotic pump (Alza Corporation, Palo Alto, CA) to allow continuous release of the molecule through the postsurgical interval. The Alzet miniosmotic pump was placed in the subcutaneous space and a delivery tube connected the pump with the site of injury at the sidewall. Only the delivery vehicle was placed in the pump of control rabbits. The abdominal wall and skin were closed in a standardized manner.